

FILED
3/3/2025

SMB

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THOMAS G. BRUTON
CLERK, U.S. DISTRICT COURT

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

)	
)	
Mary Madison)	
Plaintiff,)	Case Number: 1:23-CV-16476
)	
-)	
vs)	Honorable Judge Manish S. Shah
-)	
)	
Steve Schroeder)	
Creative Werks, LLC)	
Defendant)	

Plaintiff's Response to Defendant's Objection to Motion to Quash

Introduction

Plaintiff rejects Defendant's assertion that Plaintiff's personnel file from her current employer is necessary to establish poor performance at Plaintiff's previous job with Defendants. This assertion is unfounded, lacks merit, and serves as a pretext to obscure their true motives. The personnel file in question is irrelevant to the claims and defenses in this case and fails to meet the requisite standard for discoverability under the principles of relevance and proportionality, as outlined in Rule 26(b)(1) of the Federal Rules of Civil Procedure.

Factual History

1. Plaintiff was employed with Defendants as their Regulatory and Quality Manager beginning on September 27, 2022.
2. Plaintiff engaged in a Federal investigation and audit with the FDA on September 28-29, 2022.

3. Plaintiff raised numerous issues and non-conformances with Mr. Zicher and Defendants between October 3, 2022 and October 21, 2022.
4. On October 26, 2022, Plaintiff was suspended for presenting Defendant Schroeder with a Risk Analysis (See Exhibit A).
5. On October 26, 2022, Defendants provided a very specific reason as to Plaintiff's suspension as referenced in Exhibit A.
6. On October 26, 2022, Plaintiff was instructed to meet with Defendants outside legal counsel as a term and condition of her employment.
7. On November 1, 2022 Defendants Corporate V.P. of People contacted Plaintiff by email to meet Defendants outside legal counsel, who was alleged to be an independent factfinder.
8. On November 2, 2022, Plaintiff requested legal counsel to attend the meeting with Defendants outside legal counsel who was to be an independent fact finder.
9. On November 7, 2022, Plaintiff requested her personnel file.
10. On November 8, 2022, after requesting legal counsel, Plaintiff's paid suspension went to a non-paid suspension.
11. On November 8, 2022, Plaintiff received her personnel file (See Exhibit B).
12. On November 10, 2022 Plaintiff raised issues and concerns over the adverse employment decisions and the differential treatment amongst other things in an email to Defendants' Corporate VP of People, Gretchen Lemay (See Exhibit C).
13. On November 11, 2022 Defendants V.P. of People indicated by email that nothing was in Plaintiff's personnel file except Plaintiff's hiring documents and the suspension letter (See Exhibit D).
14. On December 20, 2022, similar concerns relative to the adverse employment actions and the differential treatment were raised during the fact finding interview with Defendants outside legal counsel.
15. On January 19, 2023, Plaintiff once again requested her personnel file.

16. On February 14, 2023, Defendants outside counsel emailed Plaintiff's request indicating that nothing new had been added by Defendants to Plaintiff's personnel file since it had been requested and produced in November of 2022.
17. On March 7, 2023 Defendants outside counsel indicated that it was aware of the claims that Plaintiff had previously raised, when Defendants made a separation offer in exchange for Plaintiff waiving her rights to any claims against Defendants.
18. Defendants' position statement to OSHA in July of 2023 did not reflect poor performance.
19. Defendants February 29, 2024 statements to the Illinois Department of Human Rights by Defendants Corporate VP of People do not reflect poor performance or that Defendants formally terminated Plaintiff.

Lack of Supporting Evidence

The Defendants have offered no evidence or legitimate basis to suggest that Plaintiff's current personnel file contains any information supporting allegations of poor performance at Defendants' place of business or how it relates to any alleged poor performance issues at the Defendants' company and how it relates to the various adverse employment actions taken by the Defendants towards Plaintiff. Specifically, Defendants are essentially asking Plaintiff's current employer has Plaintiff raised concerns about issues or employees. This request does not cut the muster and woefully falls short of Rule 26(b)(1) of the Federal Rules of Civil Procedure. Defendants' claims remain speculative and unsupported by credible evidence.

Defendants' request is a fishing expedition and is lacking in merit. Defendants' claims are unsupported. The Seventh Circuit has consistently reasoned that unsupported claims whether in oral arguments or brief do not count. *See Campania Mgmt. Co., Inc. v. Rooks, Pitts & Poust*, 290 F.3d 843, 853 (7th Cir. 2002); *United States ex rel. Feingold v. AdminaStar Fed., Inc.*, 324 F.3d 492, 494 (7th Cir. 2003); *In re Payne*, 431 F.3d 1055, 1060 (7th Cir. 2005); *IFC Credit*

Corp. v. Aliano Bros. Gen. Contractors, Inc., 437 F.3d 606, 610-611 (7th Cir. 2006); *United States v. Stevens*, 500 F.3d 625, 628-629 (7th Cir. 2007); *Woolard v. Woolard*, 547 F.3d 755 (7th Cir. 2008).

Recognition of Plaintiff's Achievements and Professionalism While Employed With Defendants

On the contrary, Plaintiff's employment record for the Defendants does not demonstrate any performance issues Plaintiff's personnel file does not support the contentions made by Defendants (See Exhibit D). Notably, during Plaintiff's tenure with the Defendants, Plaintiff was recognized for exemplary work and professionalism. Specifically:

1. **Positive Feedback for FDA Investigation Participation:** Plaintiff was copied on an email from Mr. Zicher, Director of Food Safety, to internal stakeholders, including Defendant Schroeder, for Plaintiff's involvement in the September 28–29, 2022, FDA investigation. Mr. Zicher praised the success of the inspection, attributing it to Plaintiff's and others' competence and cooperation (See Exhibit E pg.3-4). Notably, this investigation occurred during Plaintiff's first week of employment. Further, Mr. Zicher communicated these sentiments to Defendants' customers, including Teddy Cadett of Hershey, confirming that Defendants had successfully completed a routine FDA audit. (See Exhibit E pg.4)
2. **Commendation and Positive Feedback from Second-Party Auditor:** On October 6, 2022, Plaintiff successfully proctored her first second-party audit for the Defendants at their Bensenville facility. Plaintiff received commendations and positive feedback for her professionalism and readiness, as documented in an email from the supplier (See Exhibit F). Mr. Zicher further disseminated these sentiments to internal stakeholders, including Defendant Schroeder (See Exhibit G).

3. **Commendation For Resolution of Outstanding and Overdue Audit Issue(s):** Plaintiff resolved a significant and longstanding business problem related to Nestlé and deficient audit findings that had been overdue since July 2022. Mr. Zicher, Food Safety Director, personally praised and thanked Plaintiff for resolving this issue and providing a solution to a challenge that had remained unaddressed for months (See Exhibit H).

Deficiencies in Defendant's Compliance Scheme

Moreover, under the Defendants' then compliance scheme, they were unable to achieve compliance and/or identify deficiencies before audits or steward audit findings to closure from previous audit years, leading to repeated non-conforming findings (See Exhibit I). Specifically, Plaintiff was able to steward to closure an audit deficiency identified by Nestlé that had remained overdue and unresolved since the Nestlé audit in July 2022 (See Exhibit H). Plaintiff's ability to remediate outstanding and overdue deficiencies debunks the Defendant's assertions of poor performance and further demonstrates that the Defendant's claims regarding Plaintiff's alleged poor performance are unsubstantiated and does not warrant Defendants request of past and current personnel files from other employers of Plaintiff.

The Defendants' conduct reflects an attempt to shift responsibility for their own failures by engaging in pretext to create a subterfuge and to raise issues that were not addressed when the Plaintiff was suspended. Furthermore, these assertions are inaccurate and lack any nexus to the Defendants' actions of suspending the Plaintiff, withholding the Plaintiff's sign-on bonus, and suspending the Plaintiff without pay. The Plaintiff's discrediting of the employer's explanation is entitled to considerable weight, such that the Plaintiff should not be routinely required to submit evidence over and above the proof of pretext (*Reeves v. Sanderson Plumbing Prods., Inc.*, 530

U.S. 133, 140, 120 S. Ct. 2097, 147 L. Ed. 2d 105 (2000)).

Regulatory Implications

The Food Safety Modernization Act (FSMA) imposes stringent requirements for compliance in food safety and provides for individual liability for actions taken in contravention of the Act. Under FSMA, the standard for compliance is based on mitigating any risk that is reasonably foreseeable. This includes identifying, assessing, and addressing risks to prevent the introduction of unsafe products into the stream of commerce. Non-conformances that remain unaddressed represent foreseeable risks that must be resolved promptly.

In this instance, consumer complaints made to the FDA provide a reasonable basis to assert that the Defendant's non-conformances were evidenced in the stream of commerce. Failing to act on such evidence constitutes a serious regulatory breach, as FSMA requires proactive measures to protect public health and safety. Such contraventions include introducing adulterated food into the stream of commerce, providing inaccurate and misleading information to customers and regulatory agencies, and failing to maintain proper business records and compliance with 21 CFR Part 117, which establishes Current Good Manufacturing Practices (CGMPs) for food safety.

Failure to raise or address such foreseeable risks would have placed the Plaintiff in jeopardy of being held individually liable for the Defendant's malfeasance. Under the Park Doctrine, also known as the Responsible Corporate Officer (RCO) Doctrine, corporate officials, including food safety professionals, can be held personally liable for regulatory violations, even when there is no direct knowledge or intent to commit wrongdoing. This doctrine underscores the duty of individuals in positions of responsibility to identify and remediate risks that could

otherwise lead to violations of food safety laws.

The recent Blue Bell ice cream litigation highlights the consequences of failing to address foreseeable risks, where company officials were held accountable for their inability to implement and oversee adequate compliance measures, resulting in a foodborne illness outbreak. Similarly, Plaintiff's proactive efforts to identify and resolve deficiencies, such as the longstanding Nestlé issue, underscore her commitment to regulatory compliance and public safety. These actions clearly rebut the Defendant's allegations of poor performance and further expose the Defendant's attempt to mischaracterize Plaintiff's efforts to shift responsibility for their own systemic failures.

Privacy and Reputational Harm

Allowing the Defendant access to Plaintiff's personnel file from a current employer would constitute an unnecessary invasion of Plaintiff's privacy. The disclosure of sensitive employment records risks damaging Plaintiff's professional relationships with her current employer and unfairly harming Plaintiff's reputation. Courts have repeatedly emphasized the importance of protecting individuals from unwarranted intrusions into private matters, particularly when the information sought is irrelevant to the claims or defenses in the litigation.

Discovery Abuse and Fishing Expeditions

The Plaintiff rejects the Defendant's assertion that the Plaintiff's personnel file from her current employer is necessary to establish poor performance or any other issue at her previous job with the Defendants. This assertion is unfounded, lacks merit, and serves as a pretext to obscure the Defendants' true motives. The personnel file in question is irrelevant to the claims and defenses in this case and fails to meet the requisite standard for discoverability under the principles of rel-

evance and proportionality as outlined in Rule 26(b)(1) of the Federal Rules of Civil Procedure. Furthermore, this request imposes an undue burden on the Plaintiff, justifying the Motion to Quash under Rule 45(d)(3)(A) of the Federal Rules of Civil Procedure. Additionally, as per Rule 26(c), the Court may issue a protective order to prevent or limit discovery to protect against annoyance, embarrassment, oppression, or undue burden or expense. Accordingly, the Plaintiff respectfully requests that the Court grant the Motion to Quash and prevent the Defendant from accessing the Plaintiff's personnel file from past and current employers, as it has no bearing on this litigation.

Applicability to Information from Past Employers

Similar principles apply to attempts to solicit information from Plaintiff's past employers. The differing expectations, standards, and contexts between employers render such requests irrelevant and speculative. Soliciting information from past employers risks imposing further undue burdens while failing to provide any meaningful insight into the claims at issue. The same protections against invasions of privacy and fishing expeditions apply to such efforts.

Acknowledgment of Plaintiff's Performance by the Defendant

Additionally, the Defendant previously acknowledged on two (2) separate occasions that there was nothing in Plaintiff's personnel file related to poor performance. It is worth noting that the alleged reason for Plaintiff's suspension was not due to any performance issues but rather for providing a high-level risk assessment to the CEO, a demonstration of Plaintiff's commitment to transparency and responsible governance.

Differences in Employment Contexts and Performance Metrics

The Defendant's attempt to rely on Plaintiff's current employment performance to justify or

substantiate adverse actions taken at a prior job is inherently flawed. The expectations, performance metrics, and job responsibilities of one employer often differ significantly from those of another. Without accounting for such variations, any comparison of performance is speculative and lacks credibility.

Conclusion

Current work performance, shaped by entirely different circumstances and expectations, has no bearing on the adverse actions taken by Defendants. Allowing reliance on such irrelevant and speculative comparisons would set a dangerous precedent and undermine principles of fairness in discovery. Moreover, the Defendants' actions in directing a subpoena to Plaintiff's current employer and fabricating narratives to support their pretextual claims is malicious and scandalous highlight their intent to harass and damage Plaintiff's professional standing.

Allowing access to Plaintiff's current personnel file would not only impose an undue burden and invade Plaintiff's privacy but would also fail to yield any relevant information to substantiate Defendant's assertions. Discovery is not a fishing expedition, and speculative allegations do not justify intrusions into sensitive, irrelevant records.

Accordingly, the Plaintiff respectfully requests that the Court grant the Motion to Quash and prevent the Defendant from accessing the Plaintiff's personnel file from past and current employers, as it has no bearing on this litigation.

Dated: March 3, 2025

Respectfully submitted,

/S/ Mary Madison
Mary Madison
9758 S Charles
Chicago, IL 60643
6152396684
Mdj123197@aol.com

EXHIBIT A



Exhibit 19

w e r k s

1470 Brummel Ave
Elk Grove Village, IL 60007

www.creative-werks.com
630.860.2222

Notice of Suspension

October 26, 2022

Mary Madison
Quality Regulatory Manager
Via Hand Delivery

Dear Mary,

This letter is to inform you that you are being placed on a paid suspension effective immediately. This suspension will last until a full investigation into the statements made in your report and during your conversation with Steve Schroeder on Friday, October 21, 2022 can be fully completed. This review will be conducted by an outside attorney and Human Resources will make the introduction when the time comes.

During your suspension you will be paid at your regular rate of pay and have access to benefits. You will not have access to any IT systems or the building until the investigation is complete.

If you have further questions, please reach out the HR team as needed.

Thank you,

Gretchen LeMay
Head of People

Exhibit B**Attorney Interview- Tomorrow**

Gretchen LeMay <glemay@cwerksglobal.com>
To: Mary Madison <assist2law@gmail.com>

Tue, Nov 8, 2022 at 1:21 PM

Mary

Per your request, attached please find a zip file that contains your onboarding documents that you completed prior to your employment along with your suspension letter.

Thank you for providing your counsel's availability. Unfortunately, that will not be a long enough window of time to conduct the investigation as our outside counsel estimates needing 3-4 hours to speak with you.

We have been trying to have this meeting for over a week while you have been on paid suspension. Our counsel was prepared to meet with you promptly last week, but you did not show up for the meeting. Please speak with your counsel and provide availability for 3-4 hours to meet with our investigator. Until that meeting takes place you will be put on unpaid suspension. We will not continue to pay you while delays on your part remain. You will be paid through today and for any time spent meeting with our investigator.

Thank you,

Gretchen

**Gretchen LeMay**

Head of People / Corporate Vice President

1470 Brummel Ave,
Elk Grove Village, IL 60007

630-422-3587 (office)

creative-werks.com



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From: Mary Madison <assist2law@gmail.com>
Sent: Monday, November 7, 2022 5:03 PM
To: Gretchen LeMay <glemay@cwerksglobal.com>
Subject: Re: Attorney Interview- Tomorrow

Good day Ms. LeMay,

As promised here is the counselor's availability.

1:00 pm-2:00 pm on 11.18.2022

2:00 pm-3:00 pm on 11.29.2022

12:00 pm-1:00 pm on 11.30.2022

Further, I am requesting a copy of my entire personnel file under the Illinois personnel Review Act.

Thank you for your time and assistance in these matters.

Best regards,

Mary Madison

On Mon, Nov 7, 2022 at 7:38 AM Mary Madison <assist2law@gmail.com> wrote:

Good day Ms. LeMay

I will have counselor's availability this afternoon and will provide it at that time.

Best Regards

Mary Madison

On Fri, Nov 4, 2022, 8:21 AM Mary Madison <assist2law@gmail.com> wrote:

Good day Ms. LeMay,

I am awaiting a return call and will forward you that information up receipt.

Thank you for your time and assistance in this matter.

Respectfully

Mary Madison

Attorney Interview- Tomorrow**EXHIBIT C**

Mary Madison <assist2law@gmail.com>
To: Gretchen LeMay <glemay@cwerksglobal.com>

Thu, Nov 10, 2022 at 9:50 AM

Good day Ms. LeMay

Thank you for your response.

Please confirm that no documents, notes etc... have been omitted from my employee file that you sent. i.e. the file includes all documents to date related to my employment at Creative Werks.

Also, in respect to the attorney interview, this is the first mention of a time frame of 3-4 hours that was to be applied to my "interview" with the company's attorney.

I had no way of knowing the particulars just articulated to me; therefore, I was unable to articulate those details to the counselor.

Further, just to be clear, it was not my wish nor desire to have such an adverse employment action of suspension taken against me for raising operational risk/non-compliance issues to the company- Assessments that are within the scope of my employment as the Quality Regulatory Manager.

The actions taken against me were swift, punitive and harsh given the fact that no one ever took the time to speak with me for further clarification of the risks and non-compliances identified in the report dated October 20, 2022, after it was reviewed.

Nor, during the time I was being informed of my suspension, was anyone willing to review the supporting evidence that I offered during that time to underscore and corroborate the analysis.

I categorically deny that I did not show up for the interview with Creative Werks legal counsel, but assert that I was not given proper notice. The disconnect to this scenario is that I was not informed, made apprised or became aware of the "interview" until several hours prior to the "interview," when I received your voicemail. Contrarily, you indicated to me on the day of my suspension that you would be in contact with me in a couple of days. A couple of days turned into almost a week.

Further, based upon the adverse employment actions taken and; the continued actions taken against me and; the ever changing conditions of the circumstances, I exerted my rights to legal counsel.

Further, it seems as if I am again being punished for protecting my legal rights after suffering the initial adverse employment action.

Further, the conduct and actions surrounding your decision to allow me to have legal counsel seems quite disingenuous and somewhat contrived. Based upon the information that you provided, to me regarding the matter and the "interview," I passed that along to the counselor. Based upon that information, the counselor allotted the time. Failing to provide me such pertinent details as to the slated length of time of 3-4 hours for the "interview" among other things is telling. Additionally, couching it as an "interview" is also misleading and telling based upon the current information provided; making it seem more akin to a grilling session or a subsequent remedial measure to contrive reasons to support the adverse employment actions already taken against me for raising operational risk/noncompliance issues within the scope of my employment.

Furthermore, the logic surrounding this "interview" is flawed; especially, where you purport that this interview will help to better understand the issues raised in the risk analysis and further the investigation. Specifically, the logic is flawed

surrounding bringing in a 3rd party, for as you previously stated an internal matter, who is further removed from the operational and regulatory scope of your business, intervenes to help you understand the gaps in Creative Werks operation that lead to the business risks and non-compliances identified. Secondly, failing to share or apprise me of your findings, in your conclusive investigation that contravened or contradicted my assertions that led to this interview is also telling. Additionally, this type of tactic could be disadvantageous in shoring up the gaps in understanding and learning about the issues raised and identified. Last, but not least, if I had only been asked or involved in the investigation, I could have simply pointed you the FDA website that addresses most of the issues surrounding the circumstances.

I further contend that there probably would have been an issue raised by you to support your decision to further punish me by implementing further adverse employment actions upon me. I further assert and contend that these actions and adverse employment decisions are harassive and retaliatory in nature.

Again, I am fully able and willing to speak with anyone to defend the position taken in the risk analysis.

I will reach out and obtain a time that can accommodate that time frame.

Thank you kindly for your time and assistance in this matter.

Respectfully
Mary Madison
[Quoted text hidden]

10 attachments



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Attorney Interview- Tomorrow

EXHIBIT D

Gretchen LeMay <glemay@cwerksglobal.com>

Fri, Nov 11, 2022 at 11:03 AM

To: Mary Madison <assist2law@gmail.com>

Mary,

I am not going to engage in lengthy debate by email except to say that I disagree with almost everything you state in your email.

The company has provided you with all the documents you are entitled to under the Illinois Personnel Records Review Act.

I also am confirming that your interview is expected to take approximately 3-4 hours. Please provide availability at your earliest opportunity.

Thank you,



Gretchen LeMay

Head of People / Corporate Vice President

1470 Brummel Ave,
Elk Grove Village, IL 60007
630-422-3587 (office)

creative-werks.com



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From: Mary Madison <assist2law@gmail.com>

Sent: Thursday, November 10, 2022 9:50 AM

To: Gretchen LeMay <glemay@cwerksglobal.com>

Subject: Re: Attorney Interview- Tomorrow

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good day Ms. LeMay

Thank you for your response.

Please confirm that no documents, notes etc... have been omitted from my employee file that you sent. i.e. the file includes all documents to date related to my employment at Creative Werks.

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I had no way of knowing the particulars just articulated to me; therefore, I was unable to articulate those details to the counselor.

Further, just to be clear, it was not my wish nor desire to have such an adverse employment action of suspension taken against me for raising operational risk/non-compliance issues to the company- Assessments that are within the scope of my employment as the Quality Regulatory Manager.

The actions taken against me were swift, punitive and harsh given the fact that no one ever took the time to speak with me for further clarification of the risks and non-compliances identified in the report dated October 20, 2022, after it was reviewed.

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I categorically deny that I did not show up for the interview with Creative Werks legal counsel, but assert that I was not given proper notice. The disconnect to this scenario is that I was not informed, made apprised or became aware of the "interview" until several hours prior to the "interview," when I received your voicemail. Contrarily, you indicated to me on the day of my suspension that you would be in contact with me in a couple of days. A couple of days turned into almost a week.

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Again, I am fully able and willing to speak with anyone to defend the position taken in the risk analysis.

I will reach out and obtain a time that can accommodate that time frame.

Thank you kindly for your time and assistance in this matter.

Respectfully

Mary Madison

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Mary

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Thank you,



Gretchen LeMay

Head of People / Corporate Vice President

1470 Brummel Ave,
Elk Grove Village, IL 60007
630-422-3587 (office)

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From: Mary Madison <assist2law@gmail.com>
Sent: Monday, November 7, 2022 5:03 PM
To: Gretchen LeMay <glemay@cwerksglobal.com>
Subject: Re: Attorney Interview- Tomorrow

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Good day Ms. LeMay,

As promised here is the counselor's availability.

1:00 pm-2:00 pm on 11.18.2022

2:00 pm-3:00 pm on 11.29.2022

12:00 pm-1:00 pm on 11.30.2022

Further, I am requesting a copy of my entire personnel file under the Illinois personnel Review Act.

Thank you for your time and assistance in these matters.

Best regards,

Mary Madison

10

**RE: FDA Inspection Routine Inspection
- Day 2**

EXHIBIT E

From: Mary Madison

mmadison@cwerksglobal.com

To: Erich Zicher ezicher@cwerksglobal.com,

Anupam Sharma

asharma@cwerksglobal.com, Angela Knabe

aknabe@cwerksglobal.com, Patrick

Woodward pwoodward@cwerksglobal.com,

Wendy Proulx wproulx@cwerksglobal.com,

Billy King bking@cwerksglobal.com, Teresa

Noles-Puccio tnpuccio@cwerksglobal.com,

Ronald Sammeth

rsammeth@cwerksglobal.com, Steve

Schroeder sschroeder@cwerksglobal.com,

Jürgen Peters jpeters@cwerksglobal.com,

Doug Mauger dmauger@cwerksglobal.com,

Gretchen LeMay glemay@cwerksglobal.com,

Erik Peterson epeterson@cwerksglobal.com,

Ulises Rodela urodela@cwerksglobal.com,

Mart Brosas mbrosas@cwerksglobal.com,

Tim Boyd tboyd@cwerksglobal.com

Cc: cwerks_salaried_associates

cwerks_salaried_associates@cwerksglobal.com

Sent: Friday, September 30, 2:53 PM

Good day all,

Attached you will find Regulatory Observations made during the FDA inspection at Bartlett held 9.28-29.2022.

I am hopeful that this will help clarify the asks that were made and the findings noted from the inspection.

If you should have any questions comments or concerns, please feel free to reach out to me at your earliest convenience.

MDM000064CW

[[#]]

Name: Mary Madison

Phone: 773.297.9569

[[#]]

From: Erich Zicher <ezicher@cwerksglobal.com>

Sent: Thursday, September 29, 2022 9:38 PM

To: Anupam Sharma

<asharma@cwerksglobal.com>; Angela Knabe

<aknabe@cwerksglobal.com>; Mary Madison

<mmadison@cwerksglobal.com>; Patrick

Woodward <pwoodward@cwerksglobal.com>;

Wendy Proulx <wproulx@cwerksglobal.com>; Billy

King <bking@cwerksglobal.com>; Teresa Noles-

Puccio <tnpuccio@cwerksglobal.com>; Ronald

Sammeth <rsammeth@cwerksglobal.com>; Steve

Schroeder <sschroeder@cwerksglobal.com>;

Jürgen Peters <jpeters@cwerksglobal.com>; Doug

Mauger <dmauger@cwerksglobal.com>; Gretchen

LeMay <glemay@cwerksglobal.com>; Erik

Peterson <epeterson@cwerksglobal.com>; Ulises

Rodela <urodel@cwerksglobal.com>; Mart

Brosas <mbrosas@cwerksglobal.com>; Tim Boyd

<tboyd@cwerksglobal.com>

Cc: cwerks_salaried_associates

<cwerks_salaried_associates@cwerksglobal.com>

>

Subject: FDA Inspection Routine Inspection - Day

2

Hello Team,

We concluded our FDA inspection earlier this evening. High level summary of today's visit is as follows:

- Inspector arrived at 12:40 PM
- Rereviewed the complaint related to PepsiCo that was discussed yesterday
- Confirmed our refuse hauler information was consistent with Bru
- Review of Pest Control Records
- Review of Sanitary Transit Records

- Review of Food Safety Plan Process Flow Diagrams
- Review of Environmental Monitoring and Water Testing
- Review of Sanitation Processes
- Discussed Label Control
- Tour of Bartlett (Details in Closeout Meeting Observations)
- Inspector Reviewed Details of Packaging Sample Collected
- Inspector Performed Closeout Meeting (Details in Closeout Meeting Observations)
- Inspector concluded at approximately 6:25 PM

Closeout Meeting

Attendees:

- Ron Sammeth
- Erich Zicher
- Anu Sharma
- Mary Madison

Feedback: no 483's were issued for the visit. The below were discussion points that the inspector indicated will be included in the report:

1. Doc review: Pest control records demonstrated that our service provider needs to improve upon their communication
2. Doc review: Consistency of manual training records was mentioned pertaining to the printing/signing/dating of recipient names
3. Walk: Dock door #5 had light showing at the base of the door
4. Walk: EE cleaning LN 7300 was witnessed touching the floor and then using same hand to continue cleaning
5. Pepsi Complaint: Concern over lack of urgency in addressing the referenced FDA complaint (complaint received from PepsiCo: 5/28/21, CA completed by CW: 6/7/21, date of FDA referenced complaint: Oct. '21)

I would like to thank the Bartlett Leadership Team for their efforts in supporting this visit. The site

showed extremely well, aside of the two observations noted by the inspector. I would also like to express my appreciation for @Anupam, @Angela, @Mary, @Patrick, @Wendy, @Teresa, @Billy, all whom supported various parts of the inspection and document review. Thanks also for @Ronald in being available for both escalations during the inspection and being able to join in at a moment's notice for the closeout meeting.

Me and my team will be reaching out to clients as required per their respective quality manuals to inform them of the visit. Please let me know should there be any questions.

Best,



Erich Zicher

Director of Food Safety

1470 Brummel Ave.
Elk Grove Village, IL 60007

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EXHIBIT F

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Creative Werks Team,

It was an absolute pleasure meeting you all during recent audit visit. Please find attached the audit report with two minor Non-Conformances. You have 30 days from today, to address these NC's.

Below are some of the highlights from the audit.

- An outstanding well-organized audit, whole team exhibited audit readiness. The documents, records, and any other information requested was readily available.
- The owners of the programs, policies, and records were always present in the conference room during the audit to facilitate the steady flow.
- Employee Interviews, CCP checks- Performed successfully.
- Very clean and organized facility.
- Overall, the audit scored "Excellent"

Again, thank you all and keep up the good work!

Please feel free to reach out to myself or Sandy Kumar if you have any questions.

Best,

Keira Kaur Dhillon

Corporate Manager, Quality Assurance

kkaur@bdgrowers.com | Office: 916.446.8636

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EXHIBIT G

From: Tom Hillmann

<thillmann@cwerksglobal.com>

Sent: Friday, October 7, 2022 6:14 AM

To: Erich Zicher <ezicher@cwerksglobal.com>;

cwerks_salaried_associates

<cwerks_salaried_associates@cwerksglobal.com

>; cwerks_hourly_associates

<cwerks_hourly_associates@cwerksglobal.com>

Subject: RE: BDG Audit - Bensenville

Erich,

Food contact lubricant SDS with Allergen

Statements are attached, the SDS files have been
updated in our [SDS library](#).

Best Regards

Tom

From: Erich Zicher <ezicher@cwerksglobal.com>

Sent: Thursday, October 6, 2022 3:50 PM

To: cwerks_salaried_associates

<cwerks_salaried_associates@cwerksglobal.com

>; cwerks_hourly_associates

<cwerks_hourly_associates@cwerksglobal.com>

Subject: BDG Audit - Bensenville

Hello Team,

We have concluded the Blue Diamond audit for Bensenville. The auditor was very complementary of the facility's cleanliness and organization, citing that it, "looked like a Blue Diamond site." That said, there were two observations that were made that will be noted on the audit report:

- Allergens: WI 2.32 was not updated to include the new color code outlined by the OPL for the floor, and allergens were not assessed and documented for food grade lubricants (recommended that they are attached to the SDS)

RE: Nestle CAR #31

EXHIBIT H

From: Mary Madison

mmadison@cwerksglobal.com

To: Erich Zicher ezicher@cwerksglobal.com

Sent: Tuesday, October 18, 7:47 AM

Good day Erich,

You are most welcome!

When appropriate I will always make recommendations!

Kind regards,

[[#]]

Name: Mary Madison

Phone: [773.297.9569](tel:773.297.9569)

[[#]]

From: Erich Zicher <ezicher@cwerksglobal.com>

Sent: Monday, October 17, 2022 4:29 PM

To: Mary Madison

<mmadison@cwerksglobal.com>

Subject: RE: Nestle CAR #31

Thank you Mary. I appreciate how you provided a recommended course of corrective actions based upon your discussion with Donna. Terrific summary.



Erich Zicher

Director of Food Safety

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From: Mary Madison

creative werks |

MDM000058CW

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE (See Comment)	STATUS	CONFIRMED BY WHO, WHAT	2022-09-30 NOTES
Allergen Management	Are annual verifications in place?	(Repeat finding) Bensenville could not produce evidence of annual verifications on Ln 380 (and there is no control method to prevent scheduling from running peanut on the line as mentioned above)	Major	BRU - Allergen annual verification on Ln1300 performed 4/18/22, Ln 2400 performed 5/2/22; BEN - the evidence could not initially be located and the QA personnel were on vacation - evidence was found for Ln 200 - 3/31/22; Ln 250 - 8/6 & 8/20/21; Ln 380 - 5/21/21 was the last one performed; See above auditor notes for more context	8	Will audit to determine why we are behind in validations at Ben. Michaela to propose action plan based on schedule.	Angie/Michaela	1-Oct-22			Ln 250 annual verification please send the full CW paperwork for the verification believed to be recently performed; Work in progress - IT on how to systematize;
Cleaning & Disinfection	Sanitation activities are aligned with MSS (frequency and methodology)	Newly managed in M+; It was discussed that a Scorecard/Dashboard like the Maintenance Work Order system has would be ideal to manage / trend execution	Continuous Improvement	Handled in M+Lightening as a Housekeeping PM; No overdue	8						
FM Control	• Equipment under repair/re-construction/maintenance must be inspected, relating to FB, before being cleared for release.	No evidence could be provided to demonstrate equipment under repair/re-construction/maintenance is inspected (relating to FB or micro) before being cleared for release	Minor	assessing as minor due no processing equipment, the # of FM complaints received, and the overall condition of the facility	9	Need to meet with Maintenance and Sanitation to understand the workflow for items needing maintenance and how those items are then cleared for use in production.	Brian Phillips/Michael Glowa/Angie	1-Jan-23			Please define FB/FM
FM Control	Temporary repairs using inappropriate auxiliary materials such as tape, must be avoided. If temporary repairs are used, there must be a policy which includes finite period of time allowed with proper repair scheduled.	There is no mention of an allowed period of time for proper repairs to be scheduled for temporary repairs.	Minor	Generally not allowed unless waiting on a part, etc, however this was a verbal expectation	10	WI for temporary repairs will be updated with the time and materials allowed for temporary repairs	Angie	1-Oct-22			Maintenance operating procedure ← 5.8
Supplier	Is there logic in place for determining risk of supplier (high versus low)?	Recommend enhancing program to include the HARPC-required risk evaluation for the food ingredient in question to further strengthen the program (currently a peanut supplier has the same risk level as a sugar candy supplier or a coffee supplier)	Continuous Improvement	High Risk Suppliers = Food ingredient or packaging with food contact or nutritional label; High Risk require Supplier Approval; Medium risk may (service based)	10						HARPC 11.7.126

MDM000144CW

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE (See Comment)	STATUS	CONFIRMED BY WHO, WHAT	2022-09-30 NOTES
GMP Inspection	BEN & BAR - Warehouse	<p><i>Bm</i></p> <p>REPEAT FINDING: Insufficient programs in place to ensure dock doors and the use of said dock doors do not pose quality / food safety risks.</p> <p>Examples:</p> <p>BAR: 9+ dock door seals (drop curtains, wear pleats, etc) are in disrepair</p> <p>BEN -</p> <p>BEN - Door 11 had a missing window and the leveler was broken; Door 8 was missing dock leveler brushes; Door 7 leveler brushes deteriorated; Door 10 was left open 2 inches; Door 6 & others nearby - water ingress when raining; Evidence of air gaps observed in some cases when trailers are backed to the door</p>	Major	<p>BAR Dock doors 23 (repeat), 28, 51 (repeat)</p> <p>None of these doors were being used at the time, therefore estimating risk/impact; Two of the three at BAR are repeat findings from last year</p> <p>Many doors were in use and did not allocate resource to evaluate each door at the time of the audit, and as such, there may be additional doors needing attention - suggest comprehensive assessment be performed</p> <p>BRU Warehouse overall looked great and showed nice improvement from last year. Nice work Scott and team!</p> <p>New or updated procedures, training, auditing, and trending required with appropriate management commitment required to address these findings successfully</p> <p><i>When implement updates</i></p>	27	Monthly audits and proposed action with timeline will be reviewed and approved through senior leadership.	Warehouse management	15-Oct-22			
GMP Inspection	BEN - Warehouse	BEN - poor housekeeping especially around dock doors, inside and out, inclusive of excess wood splinters, trash on ground, and items stored in inappropriate locations	Minor		28	Housekeeping schedules will need to be reviewed to ensure areas are free of trash, debris, and wood splinters.	Tony Grandinetti	1-Jan-22			

MDM000154CW

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE (See Comment)	STATUS	CONFIRMED BY WHO, WHAT	202209-30 NOTES
GMP Inspection	BEN - Maintenance Shop	<p>REPEAT FINDING (from sister site): FOB risks are not adequately managed / mitigated in BEN Maintenance shop and tracked to entrance of shop</p> <p>Examples:</p> <p>Metal shavings, bolts, nuts, etc found in multiple areas of the floor and cleaning broom FILLED with shavings; No vacuum near appropriate points of use;</p>	Major	<p>BAR Maintenance shop showed significant improvement, had vacuum near the source of contamination, floor was overall clean, chemicals locked, etc. Luis joined us for the tour (2nd shift) and was very engaged and appreciative of any feedback provided. Good work.</p> <p>BRU Maintenance shop processes still considered Best Practice (Nice work Dave and team); Two associates joined us and clearly articulated their procedures to clean immediately after their work and before going out on the floor, inclusive of their uniforms</p>	29	Ben Maintenance will develop an action plan to ensure FOB are not able to leave the maintenance area. Weekly audit of the area to ensure action plan is working.	Jose Lopez	1-Oct-22			
GMP Inspection	BEN	On Ln250, scale door seals cracked and not appropriately attached to the door, creating potential FOB and micro risks	Major		30	Maintenance manager will review LN250 and submit his recommendation for needed repairs.	Jose Lopez	15-Sep-22			new pats purchased; should be in next week; look into why like that and not addressed during sanitation and pre-op
GMP Inspection	BEN	The method used to cover clean equipment is creating foreign body risks (2 or more pieces of clear plastic torn off of the plastic used to cover equipment after cleaning was found on the scale mezzanine and the steps to the mezzanine.	Major		31	Sanitation will review process for covering and uncovering equipment to determine if a different material or process is needed.	Michael Glowa	1-Oct-22			

MDM000155CW

CERTIFICATE OF SERVICE

I, Mary Madison, hereby certify that on March 3, 2025, a true and accurate copy of Plaintiff's Response to Defendants Objection to Quash was served upon all parties of record via the Court's CM/ECF electronic system to the following:

Jon D. Cohen, Esquire
Joseph R. Delehanty, Esquire
C/o Dickinson Wright PLLC
55 West Monroe St. Suite 1200
Chicago, Il 60603

Respectfully,

Mary Madison

/s/ Mary Madison_____
Mary Madison
9758 S Charles
Chicago, Il 60643
6152396684
Mdj123197@aol.com
Plaintiff (*Pro se*)